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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/531,262	Applicant(s) ZEYLIKOVICH ET AL.
	Examiner Hussein Akhavannik	Art Unit 2621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *33-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 5-8 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Claims 33-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Group I, species 2 and Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Specification

2. Claim 14 is objected to because "based setting" should be changed to "based on setting". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 3 recites the limitation "the range of frequencies from which the modulation frequency of the signal that initially illuminates the host medium is selected" in claim 1. The host medium is not explained to be initially illuminated by modulation frequency selected from a range of frequencies in claim 1 and thus, there is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-2, 4-5, 7, 10-12, 16-19, 22, 24-25, 27-28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al (U.S. Patent No. 5,999,836) in view of Alfano et al (U.S. Patent No. 5,799,656), and further in view of Essenpreis et al (U.S. Patent No. 5,713,352).

Referring to claim 1,

i. Illuminating the host medium at a plurality of different positions is illustrated by Nelson et al in figure 1b. The two light sources, source 1 and source 2, illuminate a specific region of the breast and are moved in a scan direction (arrow labeled "scan direction") in order to illuminate the entire breast over time.

ii. Detecting signals following propagation through the host medium and the abnormality within the host medium is illustrated by Nelson et al in figures 2a to 2c. The light sources illuminate the breast and the collimated detectors detect the light that is not absorbed by the breast.

iii. Creating a shadow image based upon the detected signals in which the abnormality is depicted as a suspicious region is not explicitly explained by Nelson et al. Nelson et al do obtain a shadow image of the breast, which may contain abnormal regions, by the photon detectors illustrated in figures 2a to 2c. However, Nelson et al do not explicitly explain depicting an abnormality as a suspicious region. Alfano et al do illustrate a shadow image in which the abnormalities are depicted in figures 3(a) to 3(d) and explain the depicted calcifications in column 7, lines 4-19. It is well-known in the art

of mammography to identify the abnormalities corresponding to cancer, such as the calcifications identified by Alfano et al, in a shadow (transilluminated) image in order to determine the presence and extent of breast cancer present in a patient (Alfano et al: column 9, lines 23-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to depict the abnormalities of a shadow image of the breast as suspicious regions in order to better determine the presence of breast cancer in a patient.

iv. Illuminating at least that portion of the host medium that contains the suspicious region with frequency-swept modulated signals is not explicitly explained by Nelson et al and Alfano et al. Nelson et al do explain illuminating a breast, including any suspicious regions, using multiple light sources that may range from continuous to rapidly pulsed in column 17, lines 45-47. However, Nelson et al do not explicitly explain the light sources sweeping through different pulsing frequencies. Essenpreis et al do explain modulating the light source through a range from 50 MHz to 1000 MHz in column 5, lines 26-40. Essenpreis et al explain that sweeping through a frequency range enables a system to describe the change in intensity of the transmitted light due to interaction with a biological matrix (such as breast tissue) in column 1, line 53 to column 2, line 4. By modulating the light sources of Nelson et al through a range of predetermined frequencies, the detection of breast tissue would be improved in the system of Nelson et al and Alfano et al, which would result in more accurate breast cancer detection. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to illuminate at least that portion of the host medium that contains

the suspicious region with frequency-swept modulated signals in order to more accurately detect suspicious regions in breast tissue.

v. Detecting the frequency-swept modulated signals following propagation through at least that portion of the host medium that contains the suspicious region is illustrated by Nelson et al in figures 2a to 2c. The detectors of Nelson et al are capable of detecting photons from continuous to rapidly pulsed light sources (column 17, lines 45-47) and therefore can detect the frequency-swept modulated signals of the mammography system of Nelson et al, Alfano et al, and Essenpreis et al.

vi. Characterizing the abnormality based upon the detected frequency-swept modulated signals is not explicitly explained by Nelson et al. However, Alfano et al explain characterizing the dark shadow regions of figures 3(a) to 3(d) as calcium particles in column 7, lines 16-17. In order to determine the presence of breast cancer in a patient, it is well-known in the art of mammography to determine whether the abnormal regions are malignant or benign, as explained by Alfano et al in column 9, lines 23-26. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to characterize the abnormalities detected by the frequency-swept modulated signals in the system of Nelson et al, Alfano et al, and Essenpreis et al in order to determine the presence of cancer in a patient.

Referring to claim 2, the initial illumination step comprising illuminating the host medium at a plurality of different positions with signals modulated at a frequency selected from a range of frequencies corresponds to claim 1iv. The range of frequencies used in the

mammography system of Nelson et al, Alfano et al, and Essenpreis et al is from 50MHz to 1000 MHz.

Referring to claim 4, the illumination step comprising illuminating the host medium with signals having at least two different wavelengths is illustrated by Nelson et al in figure 17 by the beams having wavelengths λ_1 and λ_2.

Referring to claim 5, the initial detecting step comprising detecting at least an amplitude of the signals following propagation through the host medium and the abnormality within the host medium is illustrated by Nelson et al in figures 2a to 2c by the detectors. The detectors determine the intensity of light (photons) passing through the breast tissue.

Referring to claim 7, illuminating at least that portion of the host medium that contains the suspicious region with signals having at least two different wavelengths is illustrated by Nelson et al in figure 17 by the beams having wavelengths λ_1 and λ_2. The same light sources may be used in the fast and slow imaging processes.

Referring to claim 10, the second illuminating step comprising positioning a light source at a position offset from the suspicious region and the second detecting step comprises moving the detector along a linear path displaced from the suspicious region is illustrated by Nelson et al in figure 5. The two source/detector combinations can be positioned anywhere along the two linear paths illustrated by the dotted arrows. The combinations can be linearly positioned at the suspected lesion during the slow processing/display explained by Alfano et al in column 8, lines 51-61.

Referring to claim 11, the second illuminating step comprising positioning a light source at a position offset from the suspicious region and the second detecting step comprises moving

the detector through a plurality of positions including at least one position aligned with the suspicious region is illustrated by Nelson et al in figure 5. The two source/detector combinations can be positioned anywhere along the two linear paths illustrated by the dotted arrows. By moving through a plurality of positions to scan the suspect lesion during the slow processing/display explained by Alfano et al in column 8, lines 51-61, each source/detector combination would move through a plurality of positions, including at least one position aligned with a suspect region.

Referring to claim 12,

i. Positioning a light source and a detector on opposite sides of the host medium in an offset relation is illustrated by Nelson et al in figure 2a. The collimated light source is positioned opposite the collimated detector.

ii. Moving the light source and the detector in tandem such that the offset relation is maintained is explained by Nelson et al in column 7, lines 27-30. Nelson et al explain moving the light source and detector in a raster scan format, wherein the light source and detector are moved in tandem across the breast in order to completely image the breast.

Referring to claim 16, the host medium being a breast and compressing the breast between a pair of plates prior to the initial illumination step is illustrated by Nelson et al in figure 8a, wherein the host medium is a breast (104) and is compressed between two plates (102a and 102b).

Referring to claim 17, the host medium being a breast and applying oil to the breast prior to the initial illumination step is explained by Nelson et al in column 17, lines 33-44. The host

medium is explained to be a breast that is covered by a gel that may act as a lubricant as explained in column 21, lines 12-16.

Referring to claim 18,

i. A light source for illuminating the host medium at a plurality of different positions is illustrated by Nelson et al in figure 1b. The two light sources, source 1 and source 2, illuminate a host medium and are moved in a scan direction (arrow labeled "scan direction") in order to illuminate a plurality of different positions.

ii. A modulator for applying frequency-swept modulation to the signals generated by the light source prior to illuminating the host medium is not explicitly explained by Nelson et al. Nelson et al do explain illuminating a breast, including any suspicious regions, using multiple light sources that may range from continuous to rapidly pulsed in column 17, lines 45-47. A modulator would be necessary in order to rapidly pulse a light source in the system of Nelson et al. However, Nelson et al do not explicitly explain the light sources sweeping through different pulsing frequencies. Essenpreis et al do explain modulating the light source through a range from 50 MHz to 1000 MHz in column 5, lines 26-40. Essenpreis et al explain that sweeping through a frequency range enables a system to describe the change in intensity of the transmitted light due to interaction with a biological matrix (such as breast tissue) in column 1, line 53 to column 2, line 4. By modulating the light sources of Nelson et al through a range of predetermined frequencies by using a modulator, the detection of breast tissue would be improved in the system of Nelson et al, which would result in more accurate breast cancer detection. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was

made to use a modulator to apply frequency-swept modulation to the signals generated by a light source prior to illuminating the host medium to more accurately detect suspicious regions in breast tissue.

iii. A detector for detecting signals following propagation through the host medium and the abnormality within the host medium is illustrated by Nelson et al in figures 2a to 2c.

iv. A display for presenting a shadow image based upon the detected signals in which the abnormality is depicted as a suspicious region is not explicitly explained by Nelson et al. Nelson et al do obtain a shadow image of the breast, which may contain abnormal regions, by the photon detectors illustrated in figures 2a to 2c. However, Nelson et al do not explicitly explain depicting an abnormality as a suspicious region. Alfano et al do illustrate a shadow image in which the abnormalities are depicted in figures 3(a) to 3(d) and explain the depicted calcifications in column 7, lines 4-19. It is well-known in the art of mammography to identify the abnormalities corresponding to cancer, such as the calcifications identified by Alfano et al, in a shadow (transilluminated) image in order to determine the presence and extent of breast cancer present in a patient (Alfano et al: column 9, lines 23-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to display depicted abnormalities of a shadow image in order to determine the presence of cancer in a patient.

v. A positioner for positioning the light source relative to the host medium such that the light source illuminate the host medium at the plurality of different positions is illustrated by Nelson et al in figure 5. Nelson et al illustrate two sets of sources and

detectors being able to scan the host medium in two directions, corresponding to the dotted arrows. However, Nelson et al do not explicitly explain positioning the light sources specifically to the proximate of the suspicious regions. Alfano et al do explain using a fast processing to determine a fast and rough image for the alignment of light scanning in column 8, lines 51-61. Thus, the slow processing will scan the suspicious regions determined in step iv of this claim for better sensitivity and accuracy. Thus, by determining the position of the suspicious regions and aligning the light source/detector combinations of Nelson et al to the suspicious regions, the detection of these regions will be improved. Therefore, it would have been obvious to one o f ordinary skill in the art at the time the invention was made to position a light source at a plurality of different positions in order to more accurately image suspicious regions of a host medium.

Referring to claim 19, the positioner for positioning the detector relative to the host medium in order to facilitate the generation of the shadow image and facilitate the characterization of the abnormality is illustrated by Nelson et al in figure 5. A light source (22) is maintained in an offset relationship to its respective detector as both move in the same direction, as indicated by the dotted arrows pointing in the same direction for both the source and the detector. Therefore, the system of Nelson et al is capable of aligning of the source/detector combination to illuminate a host medium at a plurality of different positions in order to determine both a fast processing/display and a slow processing/display of the host medium.

Referring to claim 22, the host medium being a breast and the apparatus further comprising a pair of plates separated by a distance sufficient to receive the breast of a patient is

illustrated by Nelson et al in figure 8a. The host medium is a breast (104) and the plates (102a and 102b) receive the breast.

Referring to claim 24, an opaque material filling a region defined by the plates that is unfilled by the breast is explained by Nelson et al in column 11, line 60 to column 12, line 15. The optical coupling material is explained to have a longer traveling path than the breast and therefore would be opaque.

Referring to claim 25, a background light source for illuminating any regions of separation between the opaque material and the breast is illustrated by Nelson et al in figure 8a by the light source 112. The light source illuminates the regions including the breast (104), optical coupling material (100), and any separation between the breast and the opaque material.

Referring to claim 27, the detector being a photomultiplier tube is explained by Nelson et al in column 12, lines 6-11.

Referring to claim 28, a diaphragm for selectively controlling an intensity of light that is presented to the detector is explained by Nelson et al in column 15, line 66 to column 16, line 9. Nelson et al explain that by collimating the beam, the cross-sectional area of the beam can be reduced and thus the intensity of the beam controlled. Thus, the collimator acts as a diaphragm to adjust the intensity of light presented to the detector.

Referring to claim 31,

i. A reference light source for illuminating the host medium with reference signals is illustrated by Nelson et al in figure 17. The reference light source could be any of the three light sources emitting light at λ_1, λ_2, or λ_2 wavelengths.

ii. A reference detector for detecting the reference signals following propagation through the host medium and the abnormality within the host medium is illustrated by Nelson et al in figure 17. Three detectors are illustrated that each detect light from a corresponding light source emitting a specific wavelength.

iii. A shutter for preventing further detection by the detector if the reference detector detects that an amplitude of the reference signals exceeds a predetermined threshold is explained by Nelson et al in column 6, lines 43-60. Nelson et al explain using optical shutters to analyze the radiation exiting the host medium. It is well-known in the art that shutter limit the amount of light entering a detector, such as those illustrated by Nelson et al in figure 17. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a shutter to prevent excess (above a threshold) light from entering a detector for better analysis of breast tissue.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al, Alfano et al, and Essenpreis et al as applied to claims 1-2, 4-5, 7, 10-12, 16-19, 22, 24-25, 27-28, and 31 above, and further in view of Birnbach et al (U.S. Patent No. 4,653,855).

Referring to claim 3, during the second illumination step, the signals being frequency-swept modulated across a larger range of frequencies that the range of frequencies from which the modulation frequency of the signal that initially illuminates the host medium is selected is not explicitly explained by Nelson et al, Alfano et al, or Essenpreis et al. However, Birnbach et al explain in column 2, lines 47-57 that the frequency sweep can be adjusted depending on the thermal sensitivity and absorption bands of interest in a sample being frequency swept. Birnbach et al explain that a presence of a mass will produce a perturbation in the interference fringe

pattern which would not occur in normal tissue in column 1, line 65 to column 2, line 4. Thus, in order to more accurately determine the properties of the calcifications detected by Alfano et al in the slow processing/display explained in column 8, lines 51-61, it would be beneficial to adjust (increase) the frequency band used to image the calcification (mass). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modulate the source signals across a larger frequency range in the second (slow) illumination process in order to better determine the interference fringe pattern of the suspect masses.

9. Claims 6 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al, Alfano et al, and Essenpreis et al as applied to claims 1-2, 4-5, 7, 10-12, 16-19, 22, 24-25, 27-28, and 31 above, and further in view of Tsuchiya (U.S. Patent No. 5,983,121).

Referring to claim 6, forming a ratio of the amplitude of the signals detected during the initial detecting step at each of the different wavelengths is not explicitly explained by Nelson et al, Alfano et al, or Essenpreis et al. However, Tsuchiya explain calculating the amplitude of signals detected at two separate wavelengths in column 14, lines 37-53. The ratio of the amplitudes is detected in order to calculate the specific absorptive constituent at every scanned location. By determining the absorptive constituent, malignant regions in the breast tissue can be more accurately determined, due to their differing absorptive properties. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a ratio of the amplitude of the signals detected at different wavelengths in order to better characterize regions in the scanned breast tissue in the system of Nelson et al, Alfano et al, or Essenpreis et al.

Referring to claims 8, determining a P-criteria for at least one of the plurality of positions within at least that portion of the host medium that contains the suspicious region, wherein the P-criteria is at least partially based upon coefficients of absorptivity for signals having the different wavelengths at the respective position corresponds to claim 6. The ratio of the amplitudes of the photons corresponds to the absorptivity of the signals, since the photons from the source pass through the breast tissue in the transillumination scanning of Tsuchiya. Therefore, the ratio of Tsuchiya corresponds to the claimed P-criteria.

Referring to claim 9, determining an S_{var}-criteria for at least one of the plurality of positions within at least that portion of the host medium that contains the suspicious region, wherein the S_{var}-criteria is at least partially based upon a variation in percent concentration of oxygenated hemoglobin between the abnormality and the host medium and a variation in total hemoglobin concentration between the abnormality and the host medium at the respective position is not explicitly explained by Nelson et al, Alfano et al, or Essenpreis et al. However, Tsuchiya explain determining the concentration of oxygenated hemoglobin inside a host medium, including the suspicious regions, in column 22, lines 11-28. It is well-known that different types of tissue contain different concentrations of oxygenated hemoglobin. Thus, by determining the concentration of oxygenated hemoglobin, a suspected mass can be better identified from the normal tissue. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the variation of oxygenated hemoglobin between normal tissue and a suspicious mass in order to better characterize the suspicious mass, leading to more accurate cancer detection.

10. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al, Alfano et al, and Essenpreis et al as applied to claims 1-2, 4-5, 7, 10-12, 16-19, 22, 24-25, 27-28, and 31 above, and further in view of Tsuchiya (U.S. Patent No. 5,983,121).

Referring to claim 13,

i. Illuminating a portion of the host medium at a plurality of different positions displaced from the suspicious region with signals having at least two different wavelengths is illustrated by Nelson et al in figure 1b. Two lights sources of different wavelengths illuminate a host medium across a scan direction illustrated by a solid arrow.

ii. Detecting the signals following propagation through the host medium is illustrated by Nelson et al in figure 1b. Nelson et al explain that detectors are located behind compression plate B.

iii. Determining a reference scattering coefficient and a reference absorption coefficient for the host medium based upon the detected signals is not explicitly explained by Nelson et al, Alfano et al, or Essenpreis et al. However, Chance explains using the scattering coefficient and the absorption coefficient to characterize the examined breast tissue in the abstract. By determining the scattering coefficient and the reference absorption coefficient, malignant regions in the breast tissue can be more accurately determined, due to their differing absorptive and scattering properties. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the scattering coefficient and the reference absorption coefficient for a host medium in order to better characterize regions in the scanned breast tissue in the mammography system of Nelson et al, Alfano et al, or Essenpreis et al.

Referring to claim 14, determining an absorption coefficient and a size of the abnormality based on setting a scattering coefficient of the abnormality equal to the reference scattering coefficient and further based upon the frequency-swept modulated signals that are detected following propagation through at least that portion of the host medium that contains the suspicious region is not explicitly explained by Nelson et al, Alfano et al, or Essenpreis et al. However, Chance explains determining the absorption coefficient of an abnormality corresponding to claim 13. Chance further explains determining the size of an abnormality in column 3, lines 9-10. Determining the size of an abnormality would allow the mammography system of Nelson et al, Alfano et al, and Essenpreis et al to better characterize a suspected mass. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the absorption coefficient and a size of the abnormality in order to more accurately characterize an abnormality.

Referring to claim 15, determining a location of the abnormality within the host medium following the second detecting step is explained by chance in column 3, lines 9-10. Determining the locations of the abnormalities would allow the system of Alfano et al to correctly align the source/detector combination in the slow processing/display of the abnormal regions detected, as explained by Alfano et al in column 8, lines 51-61. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the location of an abnormality in the mammography system of Nelson et al, Alfano et al, and Essenpreis et al in order to accurately align the source/detector combinations to slow scan the abnormalities detected.

11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al, Alfano et al, and Essenpreis et al as applied to claims 1-2, 4-5, 7, 10-12, 16-19, 22, 24-25, 27-28, and 31 above, and further in view of Suni et al (U.S. Patent No. 5,590,166).

Referring to claim 20, the positioner comprises at least two X-Y linear motorized stages is not explicitly explained by Nelson et al, Alfano et al, or Essenpreis et al. Though Nelson et al do illustrate linearly moving the source/detector combinations in figure 5, they do not explicitly explain using linear motorized stages. Suni et al explain using a linear motorized stage to vertically move a detection unit of a mammography system in column 2, lines 45-62. The linear motorized stages of Suni et al can be used to automatically adjust the linear potion of the source/detector combinations used by Nelson et al. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use X-Y linear motorized stages to linearly move the two source/detector combinations of the mammography system of Nelson et al, Alfano et al, or Essenpreis et al.

12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al, Alfano et al, and Essenpreis et al as applied to claims 1-2, 4-5, 7, 10-12, 16-19, 22, 24-25, 27-28, and 31 above, and further in view of Bridges et al (U.S. Patent No. 6,061,589).

Referring to claim 21, the modulator comprises a frequency-swept network analyzer is not explicitly explained by Nelson et al, Alfano et al, or Essenpreis et al. Though Essenpreis et al do explain modulating the source signal using a frequency generator (18 of figure 3) in column 5, lines 29-33, they do not explicitly explain using a network analyzer to perform the modulation. Bridges et al do explain using a network analyzer to sweep the frequency of a signal in column 18, lines 30-38. It would have been an obvious matter of design choice to modify the frequency

generator of the system of Nelson et al, Alfano et al, or Essenpreis et al by using a network analyzer to modulate the signal frequency, since the applicant has not disclosed that using a network analyzer solves any stated problem. Therefore, it appears that the frequency generator of Nelson et al, Alfano et al, or Essenpreis et al would perform equally well as the claimed network analyzer. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a frequency-swept network analyzer to sweep the source signal across a range of frequencies.

13. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al, Alfano et al, and Essenpreis et al as applied to claims 1-2, 4-5, 7, 10-12, 16-19, 22, 24-25, 27-28, and 31 above, and further in view of Gabriele et al (U.S. Patent No. 4,691,333).

Referring to claim 23, an adjustable belt extending between the plates proximate the breast and the adjustable belt being tightened about the breast such that the breast fills a region defined by the pair of plates and the adjustable belt is not explicitly explained by Nelson et al, Alfano et al, or Essenpreis et al. However, Gabriele et al illustrate using an adjustable belt to tighten a breast (11) around two plates (24 and 30) in figure 1. By using an adjustable belt, the breast can be compressed further, resulting in better transillumination scanning of the breast tissue. Therefore, it would have been obvious to one of ordinary skill in the art the time the invention was made to use an adjustable belt to compress the breast so that the breast cancer can be more accurately detected in a patient.

14. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al, Alfano et al, and Essenpreis et al as applied to claims 1-2, 4-5, 7, 10-12, 16-19, 22, 24-25, 27-28, and 31 above, and further in view of well-known prior art.

Referring to claim 26, a separation detector for measuring the distance by which two plates are separated is not explicitly explained by Nelson et al, Alfano et al, or Essenpreis et al. However, using a distance sensor in order to determine the amount of separation between two plates is well-known in the art. By using such a sensor, a large separation (above a threshold) can be detected and corrected, resulting in a more uniform breast scan. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to detect the separation distance between two plates compressing a breast in order to improve image quality and thereby improve breast cancer detection in a patient.

15. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al, Alfano et al, and Essenpreis et al as applied to claims 1-2, 4-5, 7, 10-12, 16-19, 22, 24-25, 27-28, and 31 above, and further in view of Franceschini et al (Franceschini, M.A. et al., Frequency-Domain Techniques Enhance Optical Mammography: Initial Clinical Results; Proc. Natl. Acad. Sci., USA, Vol. 94, pp. 6468-6473, June, 1997. (supplied in IDS)).

Referring to claim 29, the light source comprising a first fiber optic pigtail infrared diode laser capable of emitting signals having a power level of between 100 milliwatts and 500 milliwatts and a wavelength of between 810 nanometers and 840 nanometers is not explicitly explained by Nelson et al, Alfano et al, or Essenpreis et al. However, Franceschini et al explain using an 810 nm, 10 mW laser diode to frequency scan the breast in the abstract of this paper. Using an 100 mW to 500 mW source would have been an obvious matter of design choice in the, since the applicant only explains using these power levels on page 13, lines 25-27 of the specification and does not explain that such a power level solves any stated problem or is for any particular purpose. Therefore, it would have been obvious to one of ordinary skill in the art at

the time the invention was made to use an optical pigtail diode emitting light with a wavelength of between 810 nanometers and 840 nanometers and power between 100 milliwatts and 500 milliwatts in order to scan the breast at near-IR frequencies.

Referring to claim 30, the light source comprising a second fiber optic pigtail infrared diode laser capable of emitting signals having a power level of between 100 milliwatts and 500 milliwatts and a wavelength of between 670 nanometers and 700 nanometers is not explicitly explained by Nelson et al, Alfano et al, or Essenpreis et al. However, Franceschini et al explain using a 690 nm, 10 mW laser diode to frequency scan the breast in the abstract of this paper. Using an 100 mW to 500 mW source would have been an obvious matter of design choice in the, since the applicant only explains using these power levels on page 13, lines 25-27 of the specification and does not explain that such a power level solves any stated problem or is for any particular purpose. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an optical pigtail diode emitting light with a wavelength of between 670 nanometers and 700 nanometers and power between 100 milliwatts and 500 milliwatts in order to scan the breast at red spectrum frequencies.

16. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al, Alfano et al, and Essenpreis et al as applied to claims 1-2, 4-5, 7, 10-12, 16-19, 22, 24-25, 27-28, and 31 above, and further in view of Wist et al (U.S. Patent No. 4,945,239).

Referring to claim 32, the light source comprising a fiber optic pigtail infrared diode laser operating in a continuous wave mode and capable of emitting signals having a wavelength of between 950 nanometers and 980 nanometers is not explicitly explained by Nelson et al, Alfano et al, or Essenpreis et al. However, Wist et al do give an example of transilluminating breast

tissue with light at 950 nm wavelength in column 2, lines 51-64. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use light at 950 nm to transilluminate the breast in the system of Nelson et al, Alfano et al, and Essenpreis et al as lesions may be detected at this wavelength.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hussein Akhavannik whose telephone number is (703)306-4049. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo H. Boudreau can be reached on (703)305-4706. The fax phone numbers for the organization where this application or proceeding is assigned are (703)872-9314 for regular communications and (703)872-9314 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)305-3900.

Hussein Akhavannik H.A.
August 9, 2003

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